

### REMARKS

Claims 32-43, 63-71, and 73-78 are pending in the present application. Claim 67 has been cancelled and claims 68 and 69 have been amended, all in accordance with the Examiner's suggestions. No new matter has been added.

The present invention is directed to biocompatible bone graft materials comprising polymers (e.g., collagen) and calcium phosphate, wherein the grafts have interconnected macro-, meso-, and microporosity. The present invention is also directed to bone grafts for long bone reinforcement comprising biocompatible, resorbable sleeves of collagen and beta-tricalcium phosphate, wherein the grafts have interconnected macro-, meso-, and microporosity. The invention is further directed to grafts comprising a homogenous composite of polymers, beta-tricalcium phosphate, and a mesh, wherein the grafts have interconnected macro-, meso-, and microporosity and are shaped to conform generally to a mammalian anatomical tissue structure.

Claims 32-40, 63, and 67-70 stand rejected under 35 U.S.C. § 103(a) as allegedly unpatentable over Piez (U.S. Patent No. 4,795,467) in light of Bachand, in view of Sapienko (U.S. Patent No. 6,383,519) and further in view of Erbe (US 2002/0127720 A1). The Applicants respectfully disagree.

Piez teaches that when collagen is added to a porous, rigid mineral block, the collagen infiltrates those pores. (col. 5, lines 36-39). Piez does not teach or suggest that the porous nature of those blocks is *maintained* upon infiltration of the collagen into the pores of the porous blocks. Further, while Sapienko and Erbe teach inorganic shaped bodies comprising variable porosity, neither reference teaches how such porosity can be maintained upon treatment with a polymer, for example, collagen.

In contrast, the present invention provides for polymer-containing bone grafts that maintain macro-, meso-, and microporosity. Referring to the Specification, paragraph 37, lines 2-4, "The admixture of the collagen with the highly porous reaction product *results in a graft that is highly porous with a broad pore size distribution ....* One reason that may explain the superior resorption properties of the present invention is the *high degree of porosity*

*retained even upon admixing the collagen with the reaction product.*” (emphasis supplied). Furthermore, the mass ratio of the reaction product and the polymer, e.g., collagen, is contrary to the mineral  $\beta$ -TCP to collagen ratios one skilled in the art would find in previous bone grafts while still maintaining all the properties of an effective bone graft, for example, maintenance of porosity and pore size distribution. Specification, paragraph 42, lines 8-15. Among other capabilities, this maintained porosity provides bone graft materials that may soak and hold fluids. Specification, paragraph 49.

Piez does not teach or suggest how to maintain porosity in a graft material that has been imbibed with collagen; indeed, Piez suggests that the collagen fills the pores of a porous mineral block. (col. 5, lines 36-39). Additionally, neither Sapienko nor Erbe teaches or suggests how the macro-, meso-, and microporosity of shaped bodies can be maintained upon treatment with a polymer. The Examiner suggests that the “amount of collagen present in the graft material of the present invention is directly related to the total pore volume of the porous mineral component.” February 7, 2006 Office Action, page 7, lines 1-2. It appears that the Examiner is suggesting that the pores of the present invention become completely filled with polymer, thus eliminating the porous nature of the material. But this is not what the present invention describes. Indeed the present invention is directed to graft materials that *maintain* macro-, meso-, and microporosity. As the references cited by the Examiner fail to teach or suggest the claimed invention, the Applicants respectfully request that the rejection be withdrawn.

Claims 32, 34-43, 63-71, and 73-78 stand rejected under 35 U.S.C. 103(a) as allegedly unpatentable over Piez, in light of Bachard, in view of Sapienko, Erbe, Koblish (U.S. Patent No. 6,458,162), Lin (U.S. Patent No. 6,458,162), and Sanders (U.S. Patent No. 5,290,289). The references cited by the Examiner fail to teach or suggest the bone graft materials of the present invention that *maintain* macro-, meso-, and microporosity. For the reasons set forth above, the Applicants respectfully request that this rejection be withdrawn.

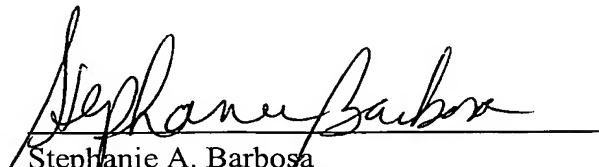
The Applicants respectfully submit that the foregoing represents a *bona fide* attempt to advance the present case to allowance. Applicants further submit that this application is now in condition for allowance. Accordingly, an indication of allowability and an early

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**PATENT**

Notice of Allowance are respectfully requested. If the Examiner believes that a telephone conference would expedite prosecution of this application, please telephone the undersigned at 215-564-8918.

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